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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,782	03/05/2002	Marie Rosier	03806.0542	8826

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EXAMINER

HAMUD, FOZIA M

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 05/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/087,782

Examiner

Fozia M Hamud

Applicant(s)

ROSIER ET AL.

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-- **Th MAILING DATE of this communication appears on the cover sheet with the correspondenc address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-40 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other:

## DETAILED ACTION

### *Election/Restriction*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7, 17-24, 30-31, 35, 40 drawn to an isolated nucleic acid molecule, comprising a specific nucleotide sequence, which encodes a specific amino acid sequence, a vector comprising said nucleic acid, a host cell comprising said nucleic acid molecule, classified in class 536, subclass 24.3.

II. Claims 8-16, drawn to a method of amplifying a region of a nucleic acid, a kit to be used in said amplification method, and a method for detecting a nucleic acid by contacting the nucleic acid with a nucleic acid reagent that hybridizes to said a nucleic acid and a kit to be used in the method, classified in class 436, subclass 504.

III. Claims 25, 35, drawn to an isolated polypeptide comprising the amino acid sequence set forth in SEQ ID NO:31 and a pharmaceutical composition comprising said polypeptide, classified in class 530, subclass 350.

IV. Claims 26-29, drawn to an antibody that selectively binds to a polypeptide and a method of detecting a polypeptide by using said antibody, classified in class 530, subclass 389.1.

V. Claims 32-33, drawn to a method of treatment by administering to a subject a nucleic acid molecule, comprising a specific nucleotide sequence, classified in class 514, subclass 44.

VI. Claim 34, drawn to a method of treatment by administering to a subject the polypeptide of SEQ ID NO:31, classified in class 514, subclass 2.

VII. Claims 36-39, drawn to a method identifying agonists or antagonist, for the polypeptide comprising SEQ ID NO:31, said method comprising the use of a host cell transfected with a nucleic encoding the polypeptide of SEQ ID NO:31, classified in class 435, subclass 7.21.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, III and IV are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function and each has an independent utility, that is distinct for each invention which cannot be exchanged. The nucleic acid of Group I can be used to make a hybridization probe or can be used in gene therapy as well as in the production of the protein of interest. The protein of Group III can be used other than to make the antibody of Group IV, such as used as a probe, or used therapeutically or diagnostically (e.g. in screening). Although the antibody of Group III can be used to obtain the nucleic acid of Group II, it can also be used in diagnostics (e.g. as a probe in immunoassays, or in immunochromatography) or it may be used therapeutically.

Inventions I and II are related as product and process of making said product. However, the inventions are distinct because the nucleic acid of Group I as claimed can be made in materially different processes, such as by using various isolation and purification protocols.

Inventions I and V are related as product and process of use. However, the inventions are distinct because nucleic acid of Group I as claimed can be used in materially different methods, such as it can be used diagnostically.

Inventions I and VII are related as product and process of use. However, the inventions are distinct because nucleic acid of Group I as claimed can be used in materially different methods, such as it can be used therapeutically.

Inventions III and VI are related as product and process of use. However, the inventions are distinct because polypeptide of Group III as claimed can be used in materially different methods, such as it can be used to raise antibodies or can be used diagnostically.

Inventions I and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the method of Group VI, neither uses nor produces the nucleic acid of Group I.

Inventions III and IV, are unrelated to inventions II, and V and VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of Groups II and V and VII neither use nor produce the polypeptide of Group III or the antibody of Groups IV.

Inventions II, V-VII are independent and distinct, each from the other, because the methods are practiced with materially different process steps for materially different purposes and each method requires a non-coextensive search because of different

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goals. The methods are distinct because each assay is performed for divergent purposes.

### **Additional Restriction Requirement**

2. The claims of Groups I, II, V, VII are drawn to a multitude of nucleic acid molecules (SEQ ID Nos:1-30) and methods of using said nucleic acid molecules. This constitutes a recitation of an implied, mis-joined Markush group that contain multiple, independent and distinct inventions. Each of the nucleic acids is independent and distinct because no common structural or functional properties are shared by these nucleic acids. Accordingly, these claims are subject to restriction under 35 U.S.C. 121.

In the event that Applicant elects the invention of Group I, II, V or VII, Applicant is additionally required to elect a single nucleic acid sequence. This requirement is not to be considered as a requirement of an election of species, since each of the compounds recited in alternative from is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention.

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter as defined by MPEP § 808.02, the Examiner has prima facie shown a serious burden of search (see MPEP § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

3. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

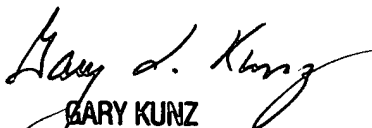
***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday, Wednesday-Thursday, 6:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4227 for regular communications and (703) 308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Fozia Hamud  
May 20, 2003

  
GARY KUNZ  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600